



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/526,836

03/04/2005

Kilwon Cho

DE1615

9374

1109 7590 06/09/2008
ANDERSON, KILL & OLICK, P.C.
1251 AVENUE OF THE AMERICAS
NEW YORK,, NY 10020-1182

EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

06/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,836	Applicant(s) CHO ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/10/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

As noted by the examiner in the last interview summary claims 8 and its dependent claims 9-11 would be allowable if rewritten in independent form with all of the limitations of base claim 1 incorporated into claim 8 and if all of the 112 issues outlined below were cleared by removing the new recitation that the hydrophobic block contains a random sequence.

Applicants amendment to the claims filed 04/10/2008 has been entered. Any rejection/objection from the previous office action filed 12/12/2007 not addressed in the action below has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

These new rejections were necessitated by applicants amendments to the claims.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically claim 1 now recites that the units of the hydrophobic block are in a random sequence, the examiner could find no support within the specification for such a limitation, in fact the term "random" is not even

mentioned within applicants specification. Furthermore applicants have not described how or where such a limitation is supported by their previous specification, claims or drawings.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claim fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in the specification at page 4 lines 5-31 and claim 8 which describe a block copolymer comprising a hydrophilic A block and a hydrophobic B block to form a diblock or triblock copolymer, formula I found within the specification and claim 8 also shows a block copolymer. In the specification and claims, applicant has clearly noted that their invention is a block copolymer, and this statement indicates that the invention is different from what is now defined in the claim(s) because a random or statistical polymer cannot be the same as a block copolymer whether it is a diblock or triblock. Random copolymers can only arise when the monomeric units that form the copolymer are random throughout the polymer, however a block copolymer has defined blocks of the same type of monomeric unit within each block, thus the blocks and the monomers that form those blocks cannot be considered as a random copolymer. To expedite the examination process the examiner searched for a block copolymer similar in nature to the description of the block copolymers within the specification and within claim 8.

Claims 1-7 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al. (US 5,702,717).

Response to Arguments

Applicant's arguments filed 04/10/2008 have been fully considered but they are not persuasive.

Applicants assert that the data from tables 1 and 2 within the specification show unexpected and advantageous results in that the micelle composition has a markedly enhanced drug content and reduced degradability when compared to a micelle not comprising an active hydrogen containing functional groups in a specified number of 1.1 to 30. Applicants assert that Cha can not meet this unexpected result or advantage since it does not suggest using an active hydrogen containing functional group in a number of 1.1 to 30.

The relevance of this assertion is unclear. As recited in the last office action the hydrophobic block of Cha had a MW preferably between 500-3,000 Daltons, this MW range would correspond to about ~4-25 units of malic acid within the block copolymer, each unit of malic acid has a free carboxylic acid functional group. Thus since Cha obviously discloses the same amount of functional groups as applicants claimed invention it is inherent that all the properties found by applicants would also be the same as the Cha reference. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established, Thus the claiming of a new use, new function or

Art Unit: 1618

unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

Applicants further assert that Cha does not teach a hydrophobic block in which the sequence of functional groups contained within the unit are random.

As noted in the 112 1st and 2nd paragraph rejections above, applicants have no support within the specification for this new limitation and this new limitation is not in accordance with the types of block copolymers described within the specification. For this reason the examiner searched for a block copolymer similar in nature to the description of the block copolymers within the specification and within claim 8, thus since Cha for the reasons outlined before does teach such a block copolymer as produced by applicants the previous rejection still stands. It is further noted by the examiner that the hydrophobic portion of Cha can be produced from mixtures of any of the disclosed monomers, thus it is the opinion of the examiner that if mixtures of hydrophobic monomers were reacted a random hydrophobic polymer would be formed. This random hydrophobic polymer would then be reacted with the hydrophilic polymer or monomer forming a block copolymer. Thus even though applicants do not have seem to have support for the limitation that the hydrophobic block contains a random sequence of monomers it appears that the Cha reference does have support for such a polymer.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

Art Unit: 1618

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

Application Number 	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/526,836	CHO ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	